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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/667,237 | 09/17/2003 | Pekka Merilainen | 2532-00320 | 6994 |

26753 7590 08/10/2006

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| EXAMINER | |
|---|---|
| BAXTER, ZOE E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3735 | |

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/667,237 | MERILAINEN ET AL. | |
| | Examiner | Art Unit | |
| | Zoe E. Baxter | 3735 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 July 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/2/05, 12/22/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 25 is missing from figure 2 and 20 and 22 are missing from figure 4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Specification*

2. The disclosure is objected to because of the following informalities: Page 8 line 21 refers to the display with reference number 22; reference 22 is previously defined as an extension strip. Reference 25 is defined on page 9 line15 there is no reference 25 in the drawings. Figure 4 definitions include reference numbers 20 and 22 but they are not labeled in the figure.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4-14 and 17-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Burton et al. (WO 2002/100267).

5. Claim 1: Burton et al. teach a unitary sensor for detecting biopotential signals on the skin of a patient, the sensor comprising (figure 37):

a. A base strip including at least three electrodes spaced along the length of the base strip, each of the sensors being operable to detect biopotential signals on the skin of the patient (page 78 lines 10-16)

b. An extension strip integrally formed with the base strip and extending from the base strip to a distal end, the extension strip including an acoustic emitter attached to the distal end (page 78 lines 15-17).

6. Claim 2: Burton et al. teaches a unitary sensor wherein the base strip is configured to be attached to the forehead of the patient and the extension strip extends from the base strip such that the acoustic emitter is positionable in an ear of the patient

when the base strip is positioned on the forehead of the patient (page 78 lines 12-18 and figure 37).

7. Claim 4: Burton et al. teach a unitary sensor of claim 1 wherein each of the plurality of sensors is operable to detect both EEG signals and AEP signals (page 78 lines 10-30).

8. Claim 5: Burton et al. teach a unitary sensor wherein the base strip includes an adhesive to secure the base strip to the patient (page 78 lines 32-33).

9. Claim 6: Burton et al. teaches an electrode system which may be usable with a connector interface (page 34 lines 26-29).

10. Claim 7: Burton et al. teach a system comprising an acoustic emitter operable to emit an audible stimulus (page 78 lines 25-26).

11. Claim 8: Burton et al. teaches a system that incorporates an EEG which would be a passive measurement module since it does not require an external stimulus to perform the measurement. Burton et al. also teaches the system to incorporate audio evoked potential analysis which would be an active measurement module since it requires an external stimulus for the measurement to be taken (page 1 lines 32-34). Burton et al. explains later that the system is designed in a modular fashion to allow for varying degrees of complexity and versatility (page 101 lines 23-25). Burton et al. also describes a programmable electrode interface system to provide a means for user guidance and operation (page 41 lines 13-20).

12. Claim 9: Burton et al. further teaches a system wherein the passive measurement module (EEG) is operable to determine the level of brain function from full awareness to deep drug-induced sleep (page 104 lines 20-25).

13. Claim 10: Burton et al. also teaches a system wherein the active measurement module (AEP monitor) is operable to determine the level of brain function from full awareness to unconsciousness (page 84 line 33-page 85 line 2).

14. Claim 11: Burton et al. teaches a system wherein the passive measurement module receives an EEG signal from the electrodes (page 101 lines 13-21).

15. Claim 12: Burton et al. teaches a system wherein the control unit is operable to select between the active measurement module and the passive measurement such that the control unit displays the current level of brain function from only one of the active measurement module and the passive measurement module at any given time (.

16. Claim 13: Burton et al. teaches a system wherein the control unit selects between the active measurement module and the passive measurement module based on a single threshold value (page 137 lines 4-15).

17. Claim 14: Burton et al. teaches a system wherein the unitary sensor includes a base strip and an extension strip, wherein the base strip is configured to be positionable on a forehead of the patient and the extension strip extends away from the base strip such that the acoustic emitter is positionable in an ear of the patient when the base strip is positioned on the forehead of the patient (page 78 lines 10-17).

18. Claim 17: Burton et al. teach a system for monitoring the level of brain function in a patient from full awareness to deep drug-induced sleep, the system comprising: a

control unit coupled to a display for displaying the level of brain function (page 41 lines 13-20), a sensor positionable on the patient and coupled to the control unit, the sensor including at least three electrodes to detect biopotential signals on the skin of the patient (page 78 lines 10-16), an acoustic emitter operable to deliver an acoustic stimulus to the patient (page 78 lines 15-17), a passive measurement module coupled to the control unit and operable to receive the biopotential signals from the sensor and determine the level of brain function (page 1 lines 32-34) an active measurement module coupled to the control unit and operable to activate the acoustic emitter to deliver acoustic stimuli and receive the biopotential signals from the sensor to determine the level of brain function, wherein the control unit is operable to select between the active measurement module and the passive measurement such that the control unit displays the current level of brain function from only one of the active measurement module and the passive measurement module at any given time (page 1 lines 32-34). It is inherent that only one measurement can be taken at a time because if the patient is being stimulated that is an active measurement and if there is no stimulus then that is an inactive measurement there is no way the two can be performed at the same time.

19. Claim 18: Burton et al. teaches a system wherein the passive measurement module is operable to determine the level of brain function from full awareness to deep drug-induced sleep (page 104 lines 20-25).

20. Claim 19: Burton et al. teach a system wherein the active measurement module is operable to determine the level of brain function from full awareness to unconsciousness (page 84 line 33-page 85 line 2).

21. Claim 20: Burton et al. teach a system wherein the control unit selects between the active measurement module and the passive measurement module based on a single threshold value (page 137 lines 4-15).

22. Claim 21: Burton et al. teaches a method for monitoring the depth of sedation in a patient from full awareness to deep drug-induced sleep characterized by the suppression of EEG, the method comprising the steps of:

a. Providing a passive measurement module operable to determine depth of sedation from full awareness to deep drug-induced sleep (page 12 line 34-page 13 line 2)

b. Providing an active measurement module operable to determine depth of sedation from full awareness to the level of losing consciousness (Page 13 lines 8-11)

c. Means for combining the information from the active measurement module and the passive measurement module to obtain the best accuracy over the entire range of sedation (page 13 lines 17-27).

23. Claim 22: Burton et al. teaches a method of wherein the passive measurement module determines the depth of sedation based on the analysis of an EEG signal from the patient (page 12 line 34-page 13 line 2).

24. Claim 23: Burton et al. teaches a method wherein the active measurement module determines the depth of sedation based upon the analysis of the response of the patient's brain to an auditory stimuli (page 13 lines 17-27).

25. Claim 24: Burton et al. teaches a method further comprising the step of positioning a unitary sensor on the patient, the unitary sensor being operable to detect the biopotential signals from the patient and deliver an auditory stimuli to the patient (page 78 lines 10-17).

26. Claim 25: Burton et al. teaches a method wherein the means for combining the information from the active measurement module and the passive measurement module includes a control unit coupled to both the active measurement module and the passive measurement module (page 13 lines 16-27).

27. Claim 26: Burton et al. describes a method in which the user has the capability of setting the control unit to select between the display of the depth of sedation from the passive measurement module and the active measurement module based upon a threshold value (page 107 lines 8-19).

28. Claim 27: Burton et al. teach a method wherein the means for combining the information from the active measurement module and the passive measurement module displays only a single depth of sedation based upon a selection between the passive measurement module and the active measurement module (page 19 line 30-page 20 line 20).

29. Claim 28: Burton et al. teach a method wherein the unitary sensor includes a base strip including at least three electrodes to detect biopotential signals on the skin of the patient and an extension strip including an acoustic emitter operable to deliver the auditory stimuli to the patient (page 78 lines 10-17).

### *Claim Rejections - 35 USC § 103*

30. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

31. Claims 3, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burden in view of Oliveira et al (U.S Patent No. 5002151). Burton et al. teaches the unitary sensor which comprises an acoustic emitter (page 78 lines 10-17). Burton et al. fails to teach the emitter is surrounded by a resilient plug that can be placed in the ear of the patient. Oliveira et al. teach an earpiece molded to fit into the ear comprising a resilient sleeve (column 1 lines 18-22). It would be obvious to one skilled in the art to use this resilient plug because as Oliveira et al teach it enhances comfort and permits one earpiece to fit nearly everyone (column 1 lines 20-22).

### *Conclusion*

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zoe E. Baxter whose telephone number is 571-272-8964. The examiner can normally be reached on Monday-Friday 7:30am-4:00pm.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zoe E. Baxter
Examiner
Art Unit 3735

ZEB

Charles A Marmor, II
SPE, Art Unit 3735